K102111

510(k) Summary

Submitter: WPR Medical AS
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DEC - 7 2010

Contact Information:
Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace
Fridley, MN 55432
763-574-1976

Submission Date: July 24, 2010

Device Name and Classification: Curvus Regular Holter System, Class II, 870.2800, Product Code MLO

Equivalent Device Identification: Vista Plus Holter Recorder, K042108
Nuvant Mobile Cardiac Telemetry System, K090696

Device Description: The Curvus Regular Holter System is a wireless mobile system for collecting a 1-lead electrocardiogram from a patient and to present the results to medical personnel such as cardiologists with the purpose to assist them to diagnose arrhythmias (heart rhythm irregularities). The Curvus Regular Holter System consists of a set of functional units including software:

- Curvus ECG Sensor – to be applied to the patient's chest to measure ECG signal
- Curvus ECG Recorder – a hand-held device to store monitored data
- Curvus ECG Examiner and Curvus ECG Analyzer – software programs to be used by medical staff for setup and closure of patient examination and for diagnostic evaluation.

Intended Use:
Curvus Sensor – Recorder:
Curvus Regular Holter is intended to record single lead (channel) surface ECG data and accelerometer data from ambulatory patients (Holter) for a period of up to 72 hours (3 days). Recorded ECG data are intended to be analyzed by Curvus Analyzer.

Curvus software suite:
Curvus Examiner is intended to program set up and closure of examination, while Curvus Analyzer analyze the retrieved data from the examination. The system is intended to be used by trained operators under the direct supervision of a trained Health Care Practitioner in a hospital or a clinic environment.

Comparison Table:

	Curvus Regular Holter System (subject device)	**Vista Plus Holter Recorder**	**Nuvant Mobile Cardiac Telemetry System**
Physiological parameters	ECG, Heart Rate, Activity	ECG, Heart rate	ECG, Heart Rate, Activity, Posture, Body Temperature, Respiration Rate Body Fluid Status
Displays findings in Real Time	No	No	Yes
Number of channels	1	1- 3	1
Number of electrodes (sensor)	1 (wireless), disposable sensor	3	1 (wireless)
Recording duration	72 hours	Up to 264 h	Not known
Communication between sensor and recorder	Radiofrequency Technology	wires	Blue Tooth Technology
Sampling rate	250 Hz	200 Hz	Not known
resolution	12	10	Not known
Dynamic range	+/- 6 mV	+/- 6 mV	Not known
Bit resolution	12 uV	12 uV	Not known
Memory type	In recorder	CF card	In sensor
Recording Full disclosure	Yes (All data can be retrieved via USB after examination)	Yes	No (Data collected when the device is first applied, irregular events and patient triggered events)
Real time built in analysis	Yes, HR analysis for real time viewed in Examiner (when connected via USB	Yes, real time HR calculation	In sensor for transmissions of irregular events
Patient trigger feature	Patient Event Button on recorder	Patient event key + voice recorder	Activated by using a magnet over the sensor
Pacer pulse detection and reporting	No	Yes	No
Replay and analysis system	Yes, viewed in Curvus Examiner and Analyzer	Yes, Holter Soft Ultima	Yes, telephonic transmission to Corventis server and analysis senter.

	Curvus Regular Holter System (subject device)	**Vista Plus Holter Recorder**	**Nuvant Mobile Cardiac Telemetry System**
PC based	Yes	Yes	Yes
OS compatibility	Windows XP	Windows 98,NT,XP	Not known
Input data	USB	CF card	GSM transmitted data
Event list display	Yes	Yes	Yes
Arrhythmia detection	Yes	Yes	Yes
ECG strip edition and printing	Yes	Yes	Yes
QT-, HRV-, A-fib-analysis	No	Yes	Not known
ST analysis	No	Yes, multichannel	No
Archiving	Yes	Yes	Yes

Summary of Testing: The Curvus Regular Holter System has been tested according to the applicable standards for EMC and Safety. The system has also been verified and validated according to the required specifications.

Conclusion: WPR believes the Curvus Regular Holter System to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

WPR Medical AS
c/o Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
435 Rice Creek Terrace
Fridley, MN 55432

DEC - 7 2010

Re: K102111
Trade/Device Name: Curvus Regular Holter System, including: Curvus Regular Holter, and Curvus Examiner and Curvus Analyzer
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II (two)
Product Code: DSI
Dated: November 18, 2010
Received: November 24, 2010

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC - 7 2010

510(k) Number (if known): K102111

Device Name: Curvus Regular Holter System

Indications For Use:

Curvus Sensor – Recorder:
Curvus Regular Holter is intended to record single lead (channel) surface ECG data and accelerometer data from ambulatory patients (Holter) for a period of up to 72 hours (3 days). Recorded ECG data are intended to be analyzed by Curvus Analyzer. The Sensor and Recorder are intended for use outside of the hospital.

Curvus software suite:
Curvus Examiner is intended to program set up and closure of examination, while Curvus Analyzer analyzes the retrieved data from the examination. The system is intended to be used by trained operators under the direct supervision of a trained Health Care Practitioner in a hospital or a clinic environment.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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